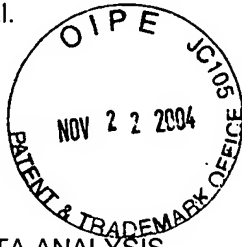


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Sachs, Jeffrey R. et al.

Serial No. 10/814,474

Filed: March 31, 2004

For: MASS SPECTROMETRY DATA ANALYSIS
TECHNIQUESArt Unit: 2881Examiner: Berman, Jack I.Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

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5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| RELATED APPLICATION | | |
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| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
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If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed with an accompanying Request for Continued Examination.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
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Respectfully submitted,



By: Sheldon O. Heber

Attorney _____ For Applicant(s)

Reg. No. 38,179

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Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1958

Date: November 19, 2004

(use as many sheets as necessary)

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| Application Number | 10/814,474 |
| Filing Date | March 31, 2004 |
| First Named Inventor | Sachs, Jeffrey R. et al. |
| Group Art Unit | 2881 |
| Examiner Name | Berman, Jack I. |

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| Sheet | 1 | of | 4 | Attorney Docket Number | 21344Y |
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| NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------|----------|--|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | | Andersen, J. et al. "Proteomic characterization of the human centrosome by protein correlation profiling", Nature, 2003, Vol. 426, pp. 570-574 |
| | | Ball, G. et al. "An integrated approach utilizing artificial neural networks and SELDI mass spectrometry for the classification of human tumours and rapid identification of potential biomarkers", Bioinformatics, 2002, Vol. 18, pp. 395-404 |
| | | Banez, L. et al. "Diagnostic Potential of Serum Proteomic Patterns in Prostate Cancer", The Journal of Urology, 2003, Vol. 170, pp. 442-446 |
| | | Chelius, D. et al. "Quantitative Profiling of Proteins in Complex Mixtures Using Liquid Chromatography and Mass Spectrometry", Journal of Proteome Research, 2002, Vol. 1, pp. 317-323 |
| | | Fang, J. et al. "Quadratic Detectors for Energy Estimation", IEEE Trans. Signal Processing, 1995, Vol. 43, pp. 2582-2594 |
| | | Flory, M. et al. "Advances in quantitative proteomics using stable isotope tags", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.), pp. S23-S29 |
| | | Frank, R. et al. "Clinical Biomarkers in Drug Discovery and Development", Nature, 2003, Vol. 2, pp. 566-580 |
| | | Friedman, D. et al. "Proteome analysis of human colon cancer by two-dimensional difference gel electrophoresis and mass spectrometry", Proteomics, 2004, Vol. 4, pp. 793-811 |
| | | Gillespie, B. et al. "Optimizing Time-Frequency Kernels for Classification", IEEE Transactions of Signal Processing, 2001, Vol. 49, pp. 485-496 |
| | | Glish, G. et al. "The Basics of Mass Spectrometry in the Twenty-First Century", Nature, 2003, Vol. 2, pp. 140-150 |
| | | Hastings, C. et al. "New algorithms for processing and peak detection in liquid chromatography/mass spectrometry data", Rapid Communications in Mass Spectrometry, 2002, Vol. 16, pp. 462-467 |
| | | Idborg-Bjorkman, H. et al. "Screening of Biomarkers in Rat Urine Using LC/Electrospray Ionization-MS and Two-Way Data Analysis", Analytical Chemistry, 2003, Vol. 75, pp. 4784-4792 |
| | | Issaq, H. et al. "SELDI-TOF MS for Diagnostic Proteomics", Analytical Chemistry, 2003, Vol. 75, pp. 149A-155A |
| | | Juang, B. et al. "On the Use of Bandpass Liftering in Speech Recognition", 1987, Vol. ASSP-35, pp. 947-954 |
| | | Lee, Y. et al. "Protein chips: from concept to practice", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.), pp. S14-S18 |

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| Examiner Signature | | Date Considered | |
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| NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------|----------|---|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | | Lieberman, S. et al. "Identification of the β cell antigen targeted by a prevalent population of pathogenic CD8+ T cells in autoimmune diabetes", Proc. Natl. Acad. Sci. USA, 2003, Vol. 100, pp. 8384-8388 |
| | | Lim, C. et al. "Current Development in LC-MS for Pharmaceutical Analysis", Biol. Pharm. Bull., 2002, Vol. 25, pp. 547-557 |
| | | Link, A. et al. "Direct analysis of protein complexes using mass spectrometry", 1999, Nature Biotechnology, Vol. 17, pp. 676-682 |
| | | Link, A. "Multidimensional peptide separations in proteomics", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.) pp. S8-S13 |
| | | Naureckiene, S. et al. "Identification of <i>HE1</i> as the Second Gene of Niemann-Pick C Disease", Science, 2000, Vol. 290, pp. 2298-2301 |
| | | Ong, S. et al. "Mass spectrometric-based approaches in quantitative proteomics", Methods, 2003, Vol. 29, pp. 124-130 |
| | | Ong, S. et al. "Properties of ^{13}C -Substituted Arginine in Stable Isotope Labeling by Amino Acids in Cell Culture (SILAC)", Journal of Proteome Research, 2003, Vol. 2, pp. 173-181 |
| | | Ong, S. et al. "Stable Isotope Labeling by Amino Acids in Cell Culture, SILAC, as a Simple and Accurate Approach to Expression Proteomics", Molecular & Cellular Proteomics, 2002, Vol. 1, pp. 376-386 |
| | | Pauler, D. et al. "Predicting time to prostate cancer recurrence based on joint models for non-linear longitudinal biomarkers and event time outcomes", Statistics in Medicine, 2002, Vol. 21, pp. 3897-3911 |
| | | Petricoin, E. et al. "Proteomic analysis at the bedside: early detection of cancer", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.), pp. S30-S34 |
| | | Petricoin, E. et al. "Serum Proteomic Patterns for Detection of Prostate Cancer", Journal of the National Cancer Institute, 2002, Vol. 94, pp. 1576-1578 |
| | | Petricoin, E. et al. "Use of proteomic patterns in serum to identify ovarian cancer", The Lancet, 2002, Vol. 359, pp. 572-577 |
| | | Pitton, J. et al. "Discrete-Time Implementation of the Cone-Kernel Time-Frequency Representation", IEEE Trans. Signal Processing, 1995, Vol. 43, pp. 1996-1998 |
| | | Qu, Y. et al. "Boosted Decision Tree Analysis of Surface-enhanced Laser Desorption/Ionization Mass Spectral Serum Profiles Discriminates Prostate Cancer from Noncancer Patients", Clinical Chemistry, 2002, Vol. 48, pp. 1835-1843 |
| | | Ryan, T. et al. "Proteomics: drug target discovery on an industrial scale", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.), pp. S45-S51 |

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| Examiner Signature | | Date Considered | |
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| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | | Sechi, S. et al. "Quantitative proteomics using mass spectrometry", Current Opinion in Chemical Biology, 2003, Vol. 7, pp. 70-77 |
| | | Sidransky, D. et al. "Serum Protein MALDI Profiling to Distinguish Upper Aerodigestive Tract Cancer Patients From Control Subjects", Journal of the National Cancer Institute, 2003, Vol. 95, pp. 1711-1717 |
| | | Smith, R. "Trends in mass spectrometry instrumentation for proteomics", Trends in Biotechnology, 2002, Vol. 20, No. 12 (Suppl.), pp. S3-S7 |
| | | Tammen, H. et al. "Expression profiling of breast cancer cells by differential peptide display", Breast Cancer Research and Treatment, 2003, Vol. 79, pp. 83-93 |
| | | Tao, W. et al. "Advances in quantitative proteomics via stable isotope tagging and mass spectrometry", Current Opinion in Biotechnology, 2003, Vol. 14, pp. 110-118 |
| | | Uchida, T. et al. "Application of a Novel Protein Biochip Technology for Detection and Identification of Rheumatoid Arthritis Biomarkers in Synovial Fluid", Journal of Proteome Research, 2002, Vol. 1, pp. 495-499 |
| | | Wang, W. et al. "Quantification of Proteins and Metabolites by Mass Spectrometry without Isotopic Labeling or Spiked Standards", Analytical Chemistry, 2003, Vol. 75, pp. 4818-4826 |
| | | Wiener, M. et al. "Differential Mass Spectrometry: A Label-Free LC-MS Method for Finding Significant Differences in Complex Peptide and Protein Mixtures", Analytical Chemistry, 2004, Vol. 76, pp. 6085-6096 |
| | | Williams, A. et al. "Compare LCMS - Extracting Component Differences in Similar LC/MS Data Sets", Advanced Chemistry Development, 2001 |
| | | Ye, B. et al. "Haptoglobin- α Subunit As Potential Serum Biomarker in Ovarian Cancer: Identification and Characterization Using Proteomic Profiling and Mass Spectrometry", Clinical Cancer Research, 2003, Vol. 9, pp. 2904-2911 |
| | | Zhu, W. et al. "Detection of cancer-specific markers amid massive mass spectral data", Proc. Natl. Acad. Sci. USA, 2003, Vol. 100, pp. 14666-14671 |
| | | Caprion Pharmaceuticals, Inc., Presentation to Merck, February 14, 2003 |
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